EXPERIMENTAL DRUG TRIALS IN CHILDREN

Author Note

Nurses plays an important role in experimental drug use or trials in children. The role of the nurses in the proper use of the drug includes the administration of drugs. A crucial role of nurses, especially when facing the current health care system dilemmas, is becoming an advocate for their clients in both hospital and community settings. The serious discussion of the draft law on clinical studies of drugs on vulnerable groups of population has been developed in social networks. Some public figures strongly opposed the bill, believing that it would allow dangerous experiments on children.

Nurses assert that clinical trials of drugs are a practice widely accepted in the world, which is conducted on the basis of strict adherence to ethical requirements. In the world, about 5,000 drugs are used to treat about 14 thousand diseases (Baiardi, et.al. 2011). Approximately the same amount of drugs is at the stage of experimental development. Before you start applying in practice, medicines must be thoroughly tested for their effectiveness and safety. Tests are initially carried out on experimental animals, and subsequently on patients who, for one reason or another, express a desire to participate voluntarily in them. This is called clinical research. Their sponsors (customers) are usually the developers and manufacturers of drugs - pharmaceutical and biotechnological companies.

Clinical studies have a history of more than 200 years since the English doctor, Edward Jenner, rubbed the contents of infected smallpox into a scratch on the body of an eight-year-old boy. He boldly believed that he could in this way provide protection against the deadly disease and called his method of vaccination. The first to use vaccination to protect their children from infections, in those years, the royal couple of Great Britain decided. Since then, vaccination has saved the lives of billions of children on the planet.

Every year more than a thousand clinical trials are conducted in the world. They are mainly performed by the leading universities of the USA, Great Britain, Europe and Southeast Asia. Participants in clinical trials are usually citizens of these countries. When it comes to drugs against diseases rarely found in developed countries, the process of clinical trials is transferred to the continents, where there is a high incidence of malaria, yellow fever and other infections. In addition, the expansion of clinical studies of drugs to other countries makes sense when there is a need to study the characteristics of local patients. In such cases, they talk about multicenter international clinical trials.

In recent years, much interest has been shown in clinical research in Singapore, South Korea and Japan. This is due to the presence in these countries of a developed technological infrastructure, human resources, a favorable legal climate, and also a friendly public perception. All these circumstances were key conditions for the investment attractiveness of these countries for transnational pharmaceutical companies that have invested significant resources in clinical research programs. It is obvious that such investments are associated with the further development of technologies and the improvement of human resources.

Nursing can develop activities to prevent the use of drugs, acting on risk factors and promoting integration in the family and in other social segments. In relation to the treatment of drug dependence, the nurse must take responsibility for nursing care and participate in the design and execution of the treatment plan established by the health team and the patient.

Nursing research in these areas and lines may analyze violence directly or indirectly. Nursing should delineate specifically the areas and lines of research related to violence. The promotion of health should be part of the activities to reduce the demand for drugs and, consequently, to control violence. The promotion of health can be understood as a process of awareness of the individual, the family and the community ( Wright, 2000). This applies to their potential, their responsibilities and individual and social rights, their sustainability, and the transformations in the human being, the environment and society. From the critical-holistic perspective, the nurse will facilitate the awareness process in different groups of the community and society.

Nursing can play a fundamental role in three health promotion strategies: i) defense of the cause (health); ii) training of health professionals and community leaders and health counselors, and iii) mediation to implement government and community measures. Nursing can promote the health of the community through the use of the following instruments: a) information; b) interpersonal education and communication; and c) the mass media ( Wright et al., 2002 ).

The nurse promotes health as a facilitator, intermediary, interlocutor, articulator, negotiator between the needs of the "client" (individual, family, community) and the different systems of society, such as health, education, legislative, transportation. The promotional-educational action is a process that is carried out in the medium and long term ( Wright et al., 2002 ). Prevention actions minimize the effect of risk factors, proposing specific strategies and measures. They should be elaborated with communities, public institutions (education, health and justice), businesses and media ( Wright et al., 2002 ).

The development of nursing interventions can be carried out through: interpersonal communication, individual contact in a consultation room, home visits, group work through awareness-raising techniques, and motivation for problems related to drug use and violence . There are different clienteles (teenagers, parents, women, schoolchildren and others), in the most diverse places. In addition, you can use the resources of mass communication, spreading messages about health and peace through various means, taking care to transmit objective, true messages, in an ethical way, not intimidating or punitive, encouraging self-care and personal development (Wright et al., 2002).

An important condition for their entry into the market is the assessment of their compliance with the original drugs in terms of efficacy and safety. For this purpose, special clinical studies are conducted, which are called bioequivalence assessment. It should be noted that the requirements for clinical trials of generics are even stricter than in the countries of the European Union. Of course, it is comfortable to realize that the quality and safety requirements are complied with in this way, but in this matter there is an excessive bureaucratization of the regulatory approval process, and this adversely affects the speed of delivery of widely sought-after drugs to the market (Cave, 2010).

The solution to the problem is seen in the liberalization of legislation in this area. For example, the United States has adopted the Cures Accelerated Network, a government program that encourages pharmaceutical and biotech companies to accelerate the development and commercialization of drugs to treat common diseases such as cancer and diabetes. This is what was mentioned in the indicated draft law on clinical studies of drugs, which caused such a heated discussion.

To conclude, potential risks can theoretically come from the pharmaceutical companies themselves, sponsors of clinical studies, and medical organizations and clinical researchers. Regarding pharmaceutical companies, the risks associated with them are leveled, thanks to the strict rules (compliance) they have adopted that require strict adherence to ethical requirements relating to clinical trials. the main tools that will mark the progress and success of nursing in the coming years are: the leadership for transformation, the use of science and technology to support professional practice, the domain of research, development and the use of thought critical with a holistic perspective, and the development of new paradigms and theoretical models.

References

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